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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,035	08/29/2005	Bent Karsten Jakobsen	006090.00018	2934

22907 7590 11/19/2008

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EXAMINER	
JUEDES, AMY E	
ART UNIT	**PAPER NUMBER**
1644	
MAIL DATE	**DELIVERY MODE**
11/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,035	JAKOBSEN ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-26 and 28-37* is/are pending in the application.

4a) Of the above claim(s) *16,19-22,24,25,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-15,17,18,23,26 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 8/12/08, are acknowledged.

Claim 27 has been cancelled.
Claims 1, 5, and 18-22 have been amended.
Claims 1, 5-26, and 28-37 are pending.

2. Claims 16, 19-22, 24-25, and 28-29 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Claims 1, 5-15, 17-18, 23, 26, and 30-32 are being acted upon.

4. The rejection of the claims under 35 U.S.C. 112 second paragraph is withdrawn in view of Applicant's amendment to the claims.

5. The rejection of the claims for obviousness type double patenting over U.S. patent 7,329,731 is withdrawn in view of Applicant's terminal disclaimer filed 8/12/08

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is

shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 1, 5-14, 17-18, 23, 26, and 30-32 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 9-20 of copending Application No. 11/667,276 in view of WO 99/18129 (of record), and WO 99/60120.

As set forth previously, The '276 application claims a soluble TCR (sTCR) comprising a TCR α and β variable region and a constant region extracellular sequence including a sequence of TRAC*01 and TRBC1*01 or TRBC2*02, wherein a disulfide bond linking cysteine residues substituted for Thr 48 of exon 1 of TRAC*01 and Ser 57 of exon 1 of TRBC1*01 or TRBC2*01. The '276 application further claims mutating or truncating the TCR constant region to remove the native disulfide bond. The '276 application further claims a sTCR associated with a superantigen (i.e. a therapeutic agent) or label. Furthermore, it would have been obvious to further include a linker sequence linking the C-terminus of the α segment to the N terminus of the β segment, since WO 99/18129 teaches the usefulness of peptide linkers in effectively positioning the Vα and Vβ chains (see pages 14-16 and 23-25, in particular). Additionally, it would have been obvious to make a sTCR, as claimed in the '276 application, specific to HLA-A2 tax, since WO 99/60120 teaches the usefulness of HLA-A2 tax specific sTCRs for therapeutic and diagnostic purposes (see pages 21-22 and 52 in particular).

This is a provisional obviousness-type double patenting rejection.

8. Claim 1, 5-15, 17-18, 23, 26, and 30-32 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 10-19, and 31 of copending Application No. 11/664,214 in view of WO 99/60120.

As set forth previously, The '214 application claims a soluble single chain TCR (scTCR) comprising a TCR α and β variable region and a constant region extracellular sequence including a sequence of TRAC*01 and TRBC1*01 or TRBC2*02, wherein a disulfide bond linking cysteine residues substituted for Thr 48 of exon 1 of TRAC*01 and Ser 57 of exon 1 of TRBC1*01 or TRBC2*01. The '214 application further claims mutating or truncating the TCR constant region to remove the native disulfide bond. The '214 application further claims a pharmaceutical composition comprising the scTCR, and a scTCR associated with a therapeutic agent. Furthermore, the '214 application claims a scTCR joined by a linker peptide comprising SEQ ID NO: 1, wherein the peptide links the C-terminus of the α segment to the N terminus of the β segment. Additionally, it would have been obvious to make a sTCR, as claimed in the '214 application, specific to HLA-A2 tax, since WO 99/60120 teaches the usefulness of HLA-A2 tax specific sTCRs for therapeutic and diagnostic purposes (see pages 21-22 and 52 in particular).

This is a provisional obviousness-type double patenting rejection.

9. Claim 1, 5-14, 17-18, 23, 26, and 30-32 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 86, and 88-89 of copending Application No. 10/532,879 in view of WO 99/18129 (of record), and WO 99/60120.

As set forth previously, The '879 application claims a soluble single chain TCR (scTCR) comprising a TCR α and β variable region and a constant region extracellular sequence including a sequence of TRAC*01 and TRBC1*01 or TRBC2*02, wherein a disulfide bond linking cysteine residues substituted for Thr 48 of exon 1 of TRAC*01 and Ser 57 of exon 1 of TRBC1*01 or TRBC2*01. Furthermore, it would have been obvious to further include a linker sequence linking the C-terminus of the α segment to the N terminus of the β segment, since WO 99/18129 teaches the usefulness of peptide linkers in effectively positioning the Vα and Vβ chains (see pages 14-16 and 23-25, in particular). Additionally, it would have been obvious to make a sTCR, as claimed in the '879 application, specific to HLA-A2 tax, since WO 99/60120 teaches the usefulness of HLA-A2 tax specific sTCRs for therapeutic and diagnostic purposes (see pages 21-22 and 52 in particular).

This is a provisional obviousness-type double patenting rejection.

10. Claim 1, 5-15, 17-18, 23, 26, and 30-32 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23, 26-35, 40-43, 5and 4-55 of copending Application No. 10/535,965 in view of WO 99/60120.

As set forth previously, The '965 application claims a soluble single chain TCR (scTCR) comprising a TCR α and β variable region and a constant region extracellular sequence including a sequence of TRAC*01 and TRBC1*01 or TRBC2*02, wherein a disulfide bond linking cysteine residues substituted for Thr 48 of exon 1 of TRAC*01 and Ser 57 of exon 1 of TRBC1*01 or TRBC2*01. The '965 application further claims mutating or truncating the TCR constant region to remove the native disulfide bond. The '965 application further claims a pharmaceutical composition comprising the scTCR, and a scTCR associated with a therapeutic agent. Furthermore, the '965 application claims a scTCR joined by a linker peptide comprising SEQ ID NO: 1, wherein the peptide links the C-terminus of the α segment to the N terminus of the β segment. Additionally, it would have been obvious to make a scTCR, as claimed in the '965 application, specific to HLA-A2 tax, since WO 99/60120 teaches the usefulness of HLA-A2 tax specific sTCRs for therapeutic and diagnostic purposes (see pages 21-22 and 52 in particular).

This is a provisional obviousness-type double patenting rejection.

Applicant's statement that the double patenting rejections be held in abeyance until the claims of this application are otherwise allowable is acknowledged.

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/G.R. Ewoldt/
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